

REMARKS

Reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks. With the above amendment, claim 13 has been canceled. Accordingly, Claim 12 is currently under consideration. The above amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application.

Priority

Without acquiescence, Applicants submit herewith a supplemental ADS reflecting the priority date of June 29, 2000 as determined in the Action.

Lack of Compliance with Sequence Rules

Applicants have amended the specification as required to identify any sequence of sufficient length with a sequence identification number and further submit herewith an amended sequence listing in compliance with the Sequence Rules set forth under 37 C.F.R. §§ 1.821-1.825. Applicants note that the Sequence Listing is provided herewith on CD-ROM in lieu of a paper copy, and is incorporated by reference into the specification. Applicants urge that no new matter has been added.

Objections to the Specification

The specification is objected to because of the alleged use of numerous improperly demarcated trademarks. The Action further notes the misspelled words "subtraction" and Bio-Rad and incorrect reference to L1-Cadherein. The specification has been amended to correct the above informalities.

With regard to "Difco", "Corixa", "Chiron", "Clontech", "Invitrogen", and "Bio-Rad", Applicants respectfully traverse the Action's assertion that the above are improperly demarcated trademarks. Applicants submit that these are company names, which is clearly indicated in the specification as filed by noting the location of the company parenthetically

following the first mention of the company name (see for example, at page 82, line 9 or at page 83, line 2). Furthermore, Applicants respectfully note that the skilled artisan would readily appreciate that these are company names. In view of these remarks, Applicants request that the objection be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph

Claim 13 stands rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the enablement requirement. In particular, the Action contends that the teachings of the specification allegedly cannot be extrapolated to the enablement of the claimed invention because the amount of guidance, direction, and exemplification set forth in the specification would allegedly not be sufficient to enable the skilled artisan to have a reasonable expectation of successfully practicing the claimed invention without need of performing an additional, undue amount of experimentation. The Action alleges that at the time of filing the prevention of cancer was largely viewed as tractable. Further, the Action contends that while immunotherapy held promise in retarding the growth of cancer, a large number of limitations associated with antibody-based therapies hampered successful application of such modalities. Additionally, the Action contends that based on the disclosure of the expression of LI-cadherin in some tumors and normal cells but not others, the skilled artisan would not automatically accept the assertion that administering an antibody that binds LI-cadherin will prevent, ablate, reduce, or inhibit cancer. The Action goes on to assert that because the specification does not explicitly disclose the level at which the polypeptide of SEQ ID NO:1081 is expressed in colon cancer relative to normal colon tissue, the skilled artisan could not reasonably expect to successfully practice the claimed invention without undue experimentation. The Action additionally cites numerous references allegedly showing that antibody-based therapy for cancer is still in its infancy and has not been successful.

Applicants respectfully traverse this rejection and submit that the claimed subject matter is enabled by the specification as filed. Nevertheless, without acquiescing to the Action's grounds for rejection, Applicants have canceled claim 13 solely to expedite prosecution and without prejudice. Applicants respectfully request that the rejection be withdrawn.

Rejections under 35 U.S.C. § 103(a)

Claim 12 stands rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Amit *et al.* (*Endocrinology* 1986 February; 118(2):825-843) in view of Berndorff *et al.* (*J Cell Biol* 1994 June; 125(6):1353-1369) and Streit *et al.* (*Recent Results Cancer Res* 1996;142:19-50). More specifically, the Action contends that Amit *et al.* disclose a method for stimulating an immune response in a warm-blooded animal comprising administering to the animal a composition comprising a physiologically acceptable carrier and an antibody that binds specifically to prolactin. The Action asserts that Amit *et al.* teach that the disclosed method provides an effective means to produce anti-PRL receptor antibodies. The Action concedes that Amit *et al.* do not disclose antibodies that specifically bind to the polypeptide of SEQ ID NO:1081. However, Berndorff *et al.* allegedly teach the LI-cadherin polypeptide. The Action further asserts that Streit *et al.* teach that adhesion receptors on the surface of cancer cells play an important role in tumor cell migration, invasion, and metastasis. In particular, the Action alleges that Streit *et al.* disclose a strong correlation between the expression of the 67-kDa laminin receptor and the metastatic potential of colorectal cancers. The Action therefore concludes that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Amit *et al.* by substituting an antibody that binds specifically to LI-cadherin, the polypeptide of SEQ ID NO:1081, because Berndorff *et al.* teach LI-cadherin. Further the Action alleges that the skilled person would have motivated to produce an antibody the specifically binds LI-cadherin receptor because the antibody could be used to elucidate the role of receptors in tumor cell migration, invasion, and metastasis.

Applicants respectfully traverse this rejection and submit that the combined primary and secondary references, taken for what they teach as a whole, do not teach or suggest the claimed invention. Therefore, Applicants submit that the claimed invention would not have been obvious to the ordinarily skilled artisan at the time of filing.

In particular, Applicants submit that, as the Action concedes, Amit, *et al.* do not disclose antibodies that specifically bind to the polypeptide of SEQ ID NO:1081. Further, while

Berndorff *et al.* may teach the sequence of LI-cadherin (*i.e.*, the polypeptide set forth in SEQ ID NO:1081), nowhere does this reference teach or suggest stimulating an immune response using antibodies against LI-cadherin. With regard to Streit *et al.*, this reference only teaches generally that adhesion receptors are expressed in certain cancers. In fact, despite discussion of other cadherins, nowhere does this references refer to LI-cadherin. Further, given that Berndorff *et al.* teach that LI-cadherin is “different from the classical cadherins such as E-, P-, and N-cadherin” (see, for example, page 1366, second paragraph of Discussion, and page 1367, last paragraph), the skilled artisan would have no reason to suspect that LI-cadherin behaves as those described by Streit *et al.* Accordingly, contrary to the assertions of the Action, the skilled artisan would have had no motivation to combine the references to arrive at Applicants’ invention. Applicants submit that a *prima facie* case of obviousness has not been established and that the claimed invention is not obvious in view of the above-cited references. Applicants respectfully request withdrawal of the rejection.

Double Patenting Rejections

Claim 13 stands provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 21 and 22 of copending Application No. 09/649,811. Claims 12 and 13 stand provisionally rejected under the same doctrine as allegedly unpatentable over claims 12 and 13 of copending Application No. 10/066,543. Specifically, the Action contends that while the conflicting claims are not identical, they are not patentably distinct from each other.

With regard to Application No. 09/649,811, Applicants submit that a Restriction Requirement was just received, mailed October 6, 2003. Applicants respectfully request that this rejection be held in abeyance until specific subject matter has been elected in this application.


With regard to Application No. 10/066,543, Applicants’ submit that this application has been abandoned. Accordingly, Applicants respectfully request withdrawal of the rejection.

The Commissioner is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants respectfully submit that all the claims remaining in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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Enclosure:

Postcard
Supplemental ADS
3 CD-ROMs containing Sequence Listing

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